

REMARKS

The above referenced application has been reviewed in light of the Final Office Action mailed November 26, 2008. Claims 1-23 are currently pending in this application. Claims 1, 15, and 21-23 have been amended by the response. It is respectfully submitted that the claims pending in the application are fully supported by the specification, introduce no new matter, and are patentable over the prior art. In view of the amendments and the remarks to follow, allowance of this application is respectfully requested.

Claims 1-7, 11, 12, 15-18, and 21-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,797,888 to Yoon (hereinafter, Yoon). Applicant respectfully submits that independent claims 1, 15, 21, 22, and 23 are each allowable over Yoon because Yoon fails to disclose each and every element of each of the independent claims. Accordingly, the rejection of claims 1, 15, 21, 22, and 23 as being anticipated under 35 U.S.C. §102(b) over Yoon is respectfully traversed.

According to §2131 of the MPEP, to anticipate a claim, the reference must teach each and every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Independent claim 1 recites an instrument introducer comprising, *inter alia*, a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical

instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to facilitate passage of a surgical instrument.

An exemplary illustration of the pocket is shown in Figures 3 and 3A, reproduced herein below. The distal end wall 20 of the distal end portion defines a pocket 30. The pocket 30 is defined by a concavely sloped wall that extends distally from the annular side wall 22 to a planar distal end wall and is further defined by having a diameter which is less than the diameter of the annular side wall 22. In this manner, a greater axial length of distal end portion 14 of introducer 10 remains in contact with an outer surface of the surgical instrument "S."

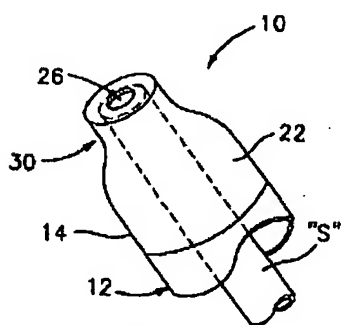


FIG. 3

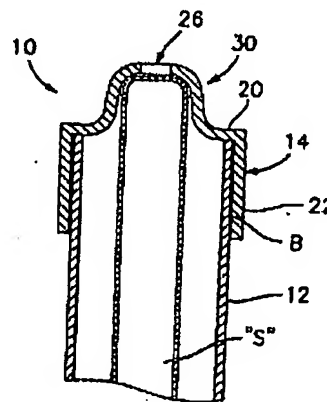
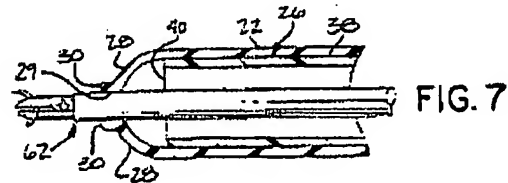
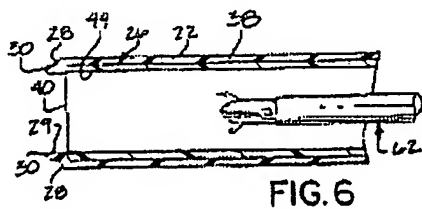


FIG. 3A

Yoon discloses a cannula 20 including an elongated tubular body 22, a seal 24 including a seal member 28 disposed along the tubular body 22, and a tubular pusher 26 disposed in the tubular body 22 and insertable through the seal 24 to move the seal member 28 from a normally closed position to an open position. As shown in Figure 6 of Yoon, reproduced herein below, lips 30 formed by seal members 28 are opened by longitudinally moving the cylindrical body 38 of tubular pusher 26 into the passage defined by seal member 28. The pusher 26 overcomes the

closing force or bias of the seal members 28 and spreads the seal members 28 apart. An instrument 62 may be inserted through the pusher 26 distally of seal 24, whereafter the pusher 26 may be retracted, as shown in Figure 7 of Yoon, so that the seal 24 is no longer held in an open position but is engaged with the instrument 62 to form a seal therewith along lips 30 and the distal edges of seal member 28.



Applicant respectfully submits that Yoon fails to anticipate each and every element of claim 1, in that Yoon fails to disclose a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket. Additionally, the distal end wall of Yoon is in the shape of a hemi-sphere and is not substantially planar as required by Applicants' claims.

Moreover, the tubular pusher 26 of Yoon controls the shape of seal 28 prior to and while instrument 62 is inserted therethrough. The pocket of Applicant's device obviates the need for a separate device, like a tubular pusher, to shape the distal end of the introducer.

Accordingly, since Yoon does not disclose or suggest each and every element of claim 1, Applicant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Since claims 2-7, 11, and 12 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-7, 11, and 12 are also not anticipated under 35 U.S.C. §102(b) over Yoon.

Independent claim 15 recites an instrument introducer comprising, *inter alia*, a hollow elongate cylindrical body and an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining a pocket having a annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall.

As discussed hereinabove with regard to claim 1, Yoon fails to teach or disclose a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall. Therefore, Applicant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Since claims 16-18 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 15, Applicant respectfully submits that claims 16-18 are also not anticipated under 35 U.S.C. §102(b) over Yoon.

Independent claims 21 and 22 both recite a method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising, *inter alia*, the step of providing an instrument introducer, wherein the instrument introducer includes a hollow tubular body and a resilient cap, the cap defining a pocket having an annular wall with an axial length such that the

annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall.

As discussed hereinabove with regard to claim 1, Yoon fails to teach or disclose, at least, a cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall. Therefore, Applicant respectfully submits that the rejection of claims 21 and 22 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Independent claim 23 recites an instrument introducer comprising, *inter alia*, a tubular body portion defining a lumen therethrough, the tubular body portion having a proximal end and a distal end; and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall having a diameter smaller than a diameter of the tubular body portion; and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of a surgical instrument and facilitate passage of the surgical instrument therethrough; wherein the distal end wall of the distal end portion includes an aperture formed therein, and further wherein the aperture has a smaller diameter than a diameter of the circular distal end wall, and wherein the aperture is provided with a region of weakened strength.

As discussed hereinabove with regard to claim 1, Yoon fails to teach or disclose a pocket having a configuration capable of increased surface contact with an outer surface of a surgical

instrument. Moreover, the distal end of the cannula in Yoon is contacted by a separate device (i.e., the tubular pusher) and not the instrument, for opening the distal end of the cannula or the seal 24 and for facilitating the passage of the instrument therethrough. Therefore, Applicant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Claims 1-13, 15-19, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,074 to Turkel et al. (hereinafter, Turkel). Applicant respectfully submits that independent claims 1, 15, and 23 are allowable over Turkel because Turkel fails to disclose each and every element of the independent claims. Accordingly, the rejection of claims 1, 15, and 23 as being anticipated under 35 U.S.C. §102(b) over Turkel is respectfully traversed.

As discussed above, independent claim 1 recites an instrument introducer comprising, *inter alia*, a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall.

Turkel discloses a protected microbiological sampling brush assembly 10 including a sampling brush 12, an inner catheter 18 which houses the brush 12, an outer catheter 22 which houses the inner catheter 18, and an elastomeric tip 24 which is rigidly attached to the distal end 22a of the outer catheter 22 and which has a weakened end defining lips 26. "[T]he inner catheter 18 is slightly longer than the outer catheter 22 and has a smaller outer diameter so that it can traverse the lumen of the outer catheter." (Col. 4, lines 44-47). As shown in Fig. 4 of

Turkel, reproduced below, lips 26a and 26b are parted by contact with distal end 18a of catheter 18 and thus, only the edge of lips 26a and 26b of tip 24 are in contact with the outer surface of catheter 18.

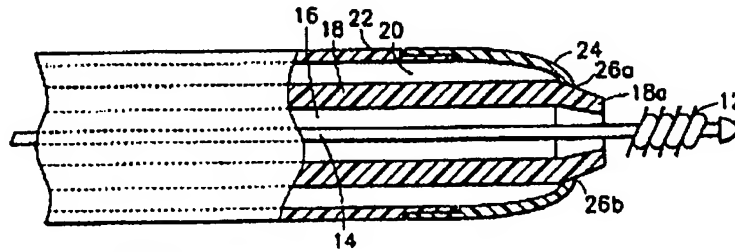


FIG. 4

Applicant respectfully submits that Turkel fails to anticipate each and every element of claim 1, in that Turkel fails to disclose a distal end portion shaped to define a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket, as only the distal end of the inner catheter contacts the outer catheter. Additionally, the distal end wall of Turkel is in the shape of a hemi-sphere and is not substantially planar as required by Applicants' claims.

Moreover, the inner catheter 18 of Turkel controls the shape of tip 24 prior to and while instrument 12 is inserted therethrough. The pocket of Applicant's device obviates the need for a separate device, like an inner catheter, to shape the distal end of the introducer.

Accordingly, since Turkel does not disclose or suggest each and every element of claim 1, Applicant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 2-13 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-14 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

Independent claim 15 recites an instrument introducer comprising, *inter alia*, a hollow elongate cylindrical body and an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall.

As discussed hereinabove with regard to claim 1, Turkel fails to teach or disclose a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall. Therefore, Applicant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

Independent claim 23 recites an instrument introducer comprising, *inter alia*, a tubular body portion defining a lumen therethrough, the tubular body portion having a proximal end and a distal end; and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall having a diameter

smaller than a diameter of the tubular body portion; and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of a surgical instrument and facilitate passage of the surgical instrument therethrough.

As discussed hereinabove with regard to claim 1, Turkel fails to teach or disclose a pocket for contacting an outer surface of a surgical instrument. The distal end of Turkel is contacted by a separate device (i.e., the inner catheter) and not the instrument, for facilitating the passage of the instrument therethrough. Therefore, Applicant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Claims 14 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al. (hereinafter, Staskin). Applicants respectfully submit that Yoon and Staskin, either alone or in combination, fail to teach or suggest the claimed apparatus.

As stated above, Yoon fails to disclose, among other things, a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall as called for in claim 1 and 15.

Staskin fails to cure the deficiencies in Yoon. Staskin discloses a sling device including a needle, dilator, and a sling material for treating urological disorders. The dilator may have different profiles, such as frusto-conical. No where does Staskin disclose or suggest an instrument introducer having a distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer

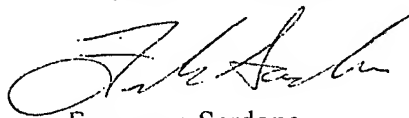
surface of a surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall.

Therefore, the prior art references, taken in any proper combination, do not teach or suggest all of the claim limitations of claims 14 and 20 as claims 14 and 20 depend from independent claims 1 and 15, respectively, and contain all of the features of the claims. For at least these reasons, *inter alia*, Applicant believes that claims 14 and 20 define over Yoon and Staskin and are in condition for allowance. Therefore, Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) has been overcome.

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



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